ARNOLD & PORTER LLP
SEAN MORRIS (State Bar No. 200368)
sean.morris@aporter.com
EMILIA P. E. MORRIS (State Bar No. 253681)
emilia.morris@aporter.com
777 South Figueroa Street, Forty-Fourth Floor
Los Angeles, California 90017-5844
Telephone: 213.243.4000
Facsimile: 213.243.4199

ANGEL A. GARGANTA (State Bar No. 163957)
angel.garganta@aporter.com
RACHEL L. CHANIN (State Bar No. 229253)
rachel.chanin@aporter.com
One Embarcadero Center, 22nd Floor
San Francisco, California 94111-3711
Telephone: (415) 356-3000
Facsimile: (415) 356-3099

Attorneys for Defendant
The Kroger Co.

UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

WESTERN DIVISION

JENNIFER RED, ET AL.,

Plaintiffs,

vs.

THE KROGER CO.,

Defendant.

Case No. 2:10-CV-01025-DMG-MAN

MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF DEFENDANT'S MOTION TO DISMISS

Hearing Date: June 28, 2010
Time: 9:30 a.m.
Place: Courtroom 7
Judge: Hon. Dolly M. Gee
Action Filed: February 11, 2010

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I. INTRODUCTION

In this action, plaintiffs Jennifer Red and Rebecca Yumul improperly seek to supplant federal law and the role of the Food and Drug Administration (FDA) by holding The Kroger Co. ("Kroger") liable for two statements on its branded products that are specifically authorized by FDA regulations -- *i.e.*, "A Cholesterol Free Food" and "0g Trans Fat Per Serving." Put simply, this case never should have been brought and should now be dismissed as a matter of law.

Federal law establishes uniform product labeling requirements, and the FDA, pursuant to the authority granted to it by that federal law, has promulgated further detailed regulations of product labeling. This comprehensive set of laws and regulations explicitly permit the two statements that plaintiffs allege are "misleading" or "unlawful" and -- importantly -- also expressly preempt this attempt by the plaintiffs to substitute their views about what statements can or cannot be made.

Specifically, with respect to plaintiffs' challenge of the statement "A Cholesterol Free Food" on two Kroger-branded products, FDA regulations provide that the term "cholesterol free" may be used on a label where, such as the case here, the product meets certain requirements. 21 C.F.R. § 101.62(d) (2010). Plaintiffs do not -- and cannot -- allege that the products at issue do not meet the federal definition that permits use of the phrase "cholesterol free" on the label; instead, plaintiffs simply and inexplicably allege that Kroger should not be permitted to use that phrase despite the clear federal law allowing it.

Similarly, the FDA regulations regarding disclosure of *trans* fat mandate that "[i]f the serving contains less than 0.5 gram, the [*trans* fat] content, when declared, shall be expressed as zero," 21 C.F.R. § 101.9(c)(2)(ii) (2010) (emphasis added), on the "Nutrition Facts" portion of the packaging. Pursuant to this regulation (adopted by the FDA because amounts of *trans* fat less than 0.5 gram cannot reliably be measured), the Kroger-branded products at issue properly list in the Nutrition Facts

box the amount of *trans* fat as zero grams per serving. Indeed, plaintiffs do not dispute that this is entirely proper.

Plaintiffs nevertheless allege that, when "0g Trans Fat Per Serving" is repeated on the product label a few inches away from the Nutrition Facts box, that statement somehow becomes wrongful. Such an allegation is contrary to additional FDA regulations, which permit this type of statement outside the Nutrition Facts box: "[T]he label or labeling of a product may contain a statement about the amount or percentage of a nutrient if . . . [t]he statement does not in any way implicitly characterize the level of the nutrient in the food and it is not false or misleading in any respect **(e.g., "100 calories" or "5 grams of fat")**, in which case no disclaimer is required." 21 C.F.R. § 101.13(i)(3) (2010) (emphasis added). Plaintiffs thus base their *trans* fat allegations on the premise that the statement "0g Trans Fat Per Serving" on the label is false and misleading -- even though (1) there is no dispute that the products satisfy the federal definition of "0g Trans Fat Per Serving;" (2) the federal regulations *require* that representation to be made in the Nutrition Facts box; and (3) the same regulations permit that statement to be repeated elsewhere on the package, since the FDA clearly does not consider the statement to be false or misleading.

The federal labeling act not only permits the statements at issue, it also expressly preempts plaintiffs' claims that try to second-guess the FDA. That labeling law provides that, for nutrition levels, states are prohibited from making "any requirement respecting any claim . . . in the label or labeling of food that is not identical to the requirement of [the act] . . . ." 21 U.S.C. § 343-1(a)(5) (2009) (emphasis added). Through this preemption provision, Congress unambiguously precluded exactly what plaintiffs are attempting here (*i.e.*, the creation of a rule through the judicial process that is different from federal law), and this action should be dismissed for that reason.

However, even if plaintiffs' claims were not preempted (which they are), plaintiffs' complaint should be dismissed for a number of other reasons as well. First, regardless of the preemptive effect of federal law, it is clear that the federal government and the FDA in particular have established a comprehensive set of rules regarding product labeling that are the result of balancing a complex set of scientific, consumer protection, and other considerations. This Court thus should decline to upset this carefully constructed balance under the doctrines of primary jurisdiction and/or equitable abstention. Moreover, plaintiffs have failed to satisfy other basic pleading requirements, such as failing to allege injury-in-fact sufficient for Article III standing or to include the requisite level of facts under Federal Rule of Civil Procedure 9(b) and that are required to avoid the "safe harbors" of California's unfair competition laws. Finally, plaintiffs' Lanham Act claim fails for the entirely independent reason that such a claim cannot be brought on behalf of consumers, as opposed to business competitors.

For all of these reasons, this Court should grant Kroger's motion to dismiss.

II. PLAINTIFFS' ALLEGATIONS

Plaintiffs allege that they "repeatedly purchased" three Kroger-branded products: "ChurnGold," "Soft Margarine," and "Value Graham Crackers." (First Amended Complaint (FAC) ¶¶ 8, 16.) Plaintiffs allege that Kroger "misleadingly" labels two of these (ChurnGold and Soft Margarine) as "Cholesterol Free Food[s]."[1] (*Id.* ¶¶ 62, 66.) Plaintiffs also allege that Kroger "misleadingly" labels two of the products (ChurnGold and Value Graham Crackers) as "0g TRANS FAT PER SERVING." (FAC ¶¶ 64, 68.) Plaintiffs assert -- without explanation -- that "[a]bsent Kroger's deceptive claims and fraudulent omissions, Plaintiffs and class members

[1] Although plaintiffs allege that the ChurnGold label states "Cholesterol Free," the labels contained within the complaint do not support that allegation. (*See* FAC ¶¶ 61-62 and accompanying pictures.)

would not have purchased" the ChurnGold, Soft Margarine, or Value Graham Crackers products. (*Id.* ¶ 74.)

Plaintiffs do not allege product liability or personal injury-based claims. They do not allege that they suffered any adverse health effects, or even that the amount of cholesterol or *trans* fat that they purportedly consumed exposed them to any potential harm. Instead, plaintiffs claim that they and other consumers somehow have suffered economic injury as a result of Kroger's labels.

Plaintiffs assert causes of action for (1) violations of the California Unfair Competition Law, Cal. Bus. & Prof. Code § 17200, *et seq.* (UCL); (2) violations of the California False Advertising Law, Cal. Bus. & Prof. Code § 17500, *et seq.* (FAL); (3) violations of the Consumer Legal Remedies Act, Cal. Civ. Code § 1750, *et seq.* (CLRA); and (4) false advertising under the Lanham Act, 15 U.S.C. § 1125, *et seq.* (FAC ¶¶ 81-104.) Plaintiffs seek to certify a nationwide class of "[a]ll persons (excluding officers, directors, and employees of Kroger) who purchased, on or after January 1, 2000, [the] Kroger ChurnGold [product], Kroger Soft Margarine, and/or Kroger Graham Crackers in the United States for their own use rather than resale or distribution." (FAC ¶ 71.)

III. LEGAL STANDARD

A complaint fails under Federal Rule of Civil Procedure 12(b)(6) if it either does not allege a cognizable legal theory or alleges insufficient facts under a cognizable legal theory. *See Robertson v. Dean Witter Reynolds, Inc.*, 749 F.2d 530, 534 (9th Cir. 1984). While the Court must assume the truth of all properly pleaded allegations of fact, "conclusory allegations of law and unwarranted inferences are insufficient to defeat a motion to dismiss." *Ove v. Gwinn*, 264 F.3d 817, 821 (9th Cir. 2001).

A case should be dismissed where the complaint fails to state a "'claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1949 (2009) (citing *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). Stripped of unsupported

legal conclusions, the factual allegations must do more than "create[] a suspicion of a legally cognizable right of action;" they must "raise a right to relief above the speculative level." *Twombly*, 550 U.S. at 555 (quotations and citations omitted).

Moreover, because plaintiffs' claims sound in fraud they are subject to the heightened pleading standard of Rule 9(b) and must be pled with particularity. *See* Fed. R. Civ. P. 9(b); *Kearns v. Ford Motor Co.*, 567 F.3d 1120 (9th Cir. 2009) (holding allegations under the CLRA and UCL failed to satisfy Rule 9(b) particularity requirement). "Averments of fraud must be accompanied by the who, what, when, where, and how of the misconduct charged." *Id.* at 1124 (quotations and citations omitted).

IV. ARGUMENT

A. Plaintiffs' Claims Are Preempted By Federal Law

The Federal Food, Drug, and Cosmetics Act, 21 U.S.C. § 301, *et seq.* (2009) ("FFDCA") establishes a comprehensive federal scheme to ensure that food is safe and labeled in an manner that does not mislead consumers. 21 U.S.C. § 341, *et seq.* (2009). In 1990, Congress passed the Nutritional Labeling and Education Act of 1990 ("NLEA"), which amended the FFDCA to include additional uniform food labeling requirements and established the now-familiar Nutrition Facts box that appears on food product labels. *See* 21 U.S.C. § 343(q)(1)-(2) (2009). In addition to the Nutrition Facts box, the FFDCA also establishes requirements for claims outside of that box, "made in the label or labeling of [a] food which expressly or by implication . . . characterize[] the level of any nutrient . . . ." 21 U.S.C. § 343(r) (2009). Section 343(r) "prohibits the use of terms that 'characterize[]' the level of any nutrient in a food unless they conform to definitions established by the FDA . . . ." *New York State Restaurant Assoc. v. N.Y. City Bd. of Health*, 556 F.3d 114, 119 (2d Cir. 2009).

The FFDCA includes a broad preemption provision that prohibits a state from imposing any labeling requirements that are not "identical to" the federal requirements.

Specifically, the FFDCA provides that states are prohibited from making "any requirement respecting any claim of the type described in section 343(r)(1) of this title [*i.e.*, the section governing characterization of the level of nutrients] made in the label or labeling of food that is not identical to the requirement of section 343(r) of this title . . . ." 21 U.S.C. § 343-1(a)(5) (2009) (emphasis added); *see also* 21 U.S.C. § 343-1(a)(4) (2009) (same language regarding preemption of statements in Nutrition Facts box); *Mills v. Giant of Maryland, LLC*, 441 F. Supp. 2d 104, 106-09 (D.D.C. 2006) (noting the breadth of the NLEA preemption clause), *aff'd on other grounds*, 508 F.3d 11 (D.C. Cir. 2007).

The phrase "not identical" refers to any "[s]tate requirement [that] directly or indirectly imposes obligations or contains provisions concerning the composition or labeling of food" that are "not imposed by or contained in the applicable provision" or that "differ from those specifically imposed by or contained in the applicable provision." 21 C.F.R. § 100.1(c)(4) (2010) (emphasis added); *see also Farm Raised Salmon Cases*, 42 Cal. 4th 1077, 1086 (Cal. 2008), *cert. denied sub nom. Albertson's, Inc. v. Kanter*, 129 S. Ct. 896 (2009).

Pursuant to the FFDCA and its amendments, the FDA has promulgated implementing regulations that specifically define and authorize the cholesterol and *trans* fatty acid ("TFA") packaging statements at issue in this case. *See* C.F.R. T. 21, Ch. I, Subch. B, Pt. 101, Refs. & Annos. (citing 21 U.S.C. § 343, *inter alia*, as statutory authority for regulations in Part 101 re "Food Labeling"). These laws, in connection with the express preemption provisions of the FFDCA, preclude plaintiffs' claims here.

1. FDA Regulations Govern -- And Permit -- The Phrase "Cholesterol Free Food" As Used On The Labels At Issue

FDA regulations define the circumstances in which "[t]he term[] 'cholesterol free' . . . may be used on the label or in the labeling of foods." *See* 21 C.F.R. § 101.62(d) (2010). Under the regulations, a label can declare a product to be a

"cholesterol free" food if it meets certain requirements, such as containing "less than 2 mg of cholesterol per reference amount customarily consumed and per labeling serving." *Id.* at § 101.62(d)(1)(i)(A).

The FDA reached this definition of "cholesterol free" based on a science-based, rigorous assessment and after weighing comments from various stakeholders. Ultimately, the FDA adopted the definition of "cholesterol free" using the under-two-milligram benchmark, because lower levels of cholesterol are not reliably detectable.

> Most of the comments on the definition of the term 'cholesterol free' supported the definition … of less than 2 mg of cholesterol per serving. A few comments disagreed. . . . The agency is not persuaded that the proposed value of less than 2 mg of cholesterol per serving should be changed or needs to be defined on the label. The agency selected this value because it represents the typical limit of reliable detection for existing analytical methods. A value of zero is not an option because it is analytically impossible to measure. Furthermore, 2 mg per serving is low enough compared to the DRV for cholesterol, which is 300 mg, to be considered dietarily and physiologically insignificant.[2]

Plaintiffs do not allege that the Kroger labels mis-use the phrase "Cholesterol Free Food" as defined by the FDA. Nor could they. Instead, plaintiffs baldly assert that the use of this phrase, which the FDA has determined to be proper, is nevertheless "highly misleading" and should subject Kroger to liability.

2. FDA Regulations Govern -- And Permit -- The Phrase "0g Trans Fat Per Serving" As Used On The Labels At Issue

In 2003, the FDA issued its regulation governing the proper disclosures of TFA levels in foods. Where a product contains more than 0.5 gram of total fat in a serving (as with the products at issue here), the Nutrition Facts box must include a

[2] *See* Request for Judicial Notice ISO Defendant's Motion to Dismiss ("RFJN") Ex. A, Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definition of Terms; Definitions of Nutrient Content Claims for the Fat, Fatty Acid, and Cholesterol Content of Food, 58 Fed. Reg. 2302, 2332 (January 6, 1993).

statement regarding the level of *trans* fat contained in the product. 21 C.F.R. § 101.9(c)(2)(ii) (2010). However, in that situation, the level of *trans* fat also must be reported as **zero**, if the serving contains less than 0.5 gram of *trans* fat per serving. The law is unambiguous regarding this requirement: "If the serving contains less than 0.5 gram [*trans* fat], the content, when declared, shall be expressed as zero." 21 C.F.R. § 101.9(c)(2)(ii) (2010) (emphasis added).

Like the regulation regarding "cholesterol free," the FDA's decision to define anything less than 0.5 gram of *trans* fat as "zero" is the result of extensive rule-making procedures. Using these procedures, the FDA repeatedly has emphasized that the under 0.5 gram benchmark definition of "zero" is appropriate, because levels of *trans* fat below that level are not reliably detectable.[3]

The FDA also has promulgated a regulation that expressly permits representations that are made within the Nutrition Facts box (such as those representations regarding the defined levels of *trans* fat) to appear elsewhere on the label, so long as those statements are consistent with the statements in the Nutrition Facts box to ensure accuracy and avoid confusion. 21 C.F.R. § 101.13(c) (2010). Thus, outside the Nutrition Facts box, "label or labeling of a product may contain a statement about the amount or percentage of a nutrient if:"

> The statement does not in any way implicitly characterize the level of nutrient in the food and is not false or misleading in any respect (e.g., "100 calories" or "5 grams of fat"), in which case no disclaimer is required.

[3] *See, e.g.*, RFJN Ex. B, Food Labeling: Trans Fatty Acids in Nutritional Labeling, Nutrient Content Claims, and Health Claims, 64 Fed. Reg. 62746, 62758 (Nov. 17, 1999) ("The petitioner's suggestion that the definition of 'saturated fat free' be changed to less than 0.5 g of saturated and trans fat combined is not analytically feasible because it would require accurate measurement of both saturated fat and trans fat at levels significantly below 0.5 g. In the absence of more sensitive methods, which the petitioner did not provide, it is not appropriate for the agency to set criteria **that cannot be adequately analyzed**.") (emphasis added); RFJN Ex. C, Food Labeling: Trans Fatty Acids in Nutrition Labeling, Nutrient Content Claims, and Health Claims, 68 Fed. Reg. 41434, 41463 (July 11, 2003) (emphasis added) (rejecting listing to nearest tenth or hundredth of a gram, discussing problems with detection at these levels, and explaining that the 0.5 increment for listing *trans* fat is consistent with increments used for listing total fat and saturated fat).

21 C.F.R. § 101.13(i) (2010).

The FDA requires consistency between statements made inside and outside the Nutrition Box because it views differences between statements in those two locations as potentially "confusing to consumers." *See* RFJN Ex. D, Food Labeling: Nutrient Content Claims . . ., 58 Fed. Reg. 44020, 44025 cmt. 11 (Aug. 18, 1993); *see also* RFJN Ex. B, 64 Fed. Reg. at 62755 ("Also, one of the principles used by the agency in establishing nutrient content claims is that the nutrient must be declared in the nutrition label so that the claim is verifiable by reference to the nutrition label.") (emphasis added). In fact, the FDA has taken, and continues to take, enforcement action based on this view. For example, the FDA recently sent a warning letter to a food manufacturer that, among other things, made claims outside the Nutrition Facts panel that were *different* from information inside the panel. *See* RFJN Ex. E, Warning Letter from FDA to Ole' Mexican Foods, Inc., dated Nov. 6, 2007, available at http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2007/ucm076568.htm (citing violation of regulations based on inconsistency of statements in Nutrition Facts panel and other claims on the label)).

Plaintiffs do not allege that the representation of zero grams *trans* fat inside the Nutrition Facts box on the labels at issue does not comply with the law or that those statements could be the basis for their claims. Instead, plaintiffs assert only that the same statement made a few inches away on a different portion of the label is actionable because it is "misleading."

3. Plaintiffs' Claims Are Preempted

Not only do general principles of federal preemption under the United States Constitution apply here, *see Maryland v. Louisiana*, 451 U.S. 725, 746 (1981), but, as discussed above, the FFDCA also includes an express preemption provision that bars plaintiffs' claims. *See* 21 U.S.C. § 343-1(a)(5) (2009) (preemption regarding nutrient content statements).

Courts consistently have acknowledged that the FDA's regulations of nutrient content statements, like those at issue here, preempt state laws that attempt to impose requirements that are different from the FDA's rules. As one court has put it, "states are broadly preempted from regulating voluntary claims that characterize the level of any nutrient . . . [S]tates are precluded under § 343-1(a)(5) from establishing requirements for 'claims,' . . . unless the requirements are identical to federal requirements." *New York State Restaurant Assoc. v. New York City Bd. of Health*, 509 F. Supp. 2d 351, 358 (S.D.N.Y. 2007). A voluntary statement outside the Nutritional Facts panel "is a 'claim' subject to § 343(r), the attendant FDA regulations, and, significantly, the broader preemption provision found in § 343-1(a)(5) . . ." *Id.* at 361. "Section 343-1(a)(5) . . . preempts any state regulation of nutrient content claims . . . that 'is not identical to the requirement[s] of section 403(r).'" *Id.* at 362. *See also New York State Restaurant Association*, 556 F.3d at 120 ("Section 343-1(a)(5), which relates to Section 343(r), expressly preempts state or local governments from imposing any requirement on nutrient content claims made by a food purveyor 'in the label or labeling of food that is not identical to the requirements of [S]ection 343(r) . . . .' [S]tates . . . are preempted from adopting nutrient claim laws as defined by Section 343(r).") (emphasis added). Accordingly, plaintiffs' attempt to use the judicial process to regulate nutrient content statements such as "A Cholesterol Free Food" and "0g Trans Fat Per Serving" is preempted.

As discussed *supra*, the FDA regulations explicitly govern -- and authorize -- statements on a product's label that a food is "Cholesterol Free." 21 C.F.R. § 101.62(d) (2010). Notwithstanding this express authorization, plaintiffs challenge Kroger's proper use of the phrase "A Cholesterol Free Food" on its packaging. (FAC ¶¶ 60, 62-63, 66-67.) Ultimately, plaintiffs' theory is that Kroger should be held liable for including on its products' packaging a cholesterol statement expressly permitted by the FDA. Such an allegation is clearly preempted.

Plaintiffs' allegations regarding Kroger's "0g Trans Fat Per Serving" statements are similarly preempted. Under 21 C.F.R. § 101.9(c)(2)(ii) and 21 C.F.R. § 101.13(i)(3), discussed *supra*, the FDA has set forth a clear definition of the term "0g Trans Fat" per serving and the circumstances under which that defined statement may be made on a product's packaging. While plaintiffs allege that the statement "0g Trans Fat Per Serving" is "literally false" and that Kroger should not be permitted to make it (FAC ¶¶ 65, 69 and Prayer for Relief), the fact is that the FDA has determined such a statement is permissible and not misleading. Plaintiffs cannot be permitted to trump the FDA's determination.[4]

B. Plaintiffs' Complaint Should Be Dismissed For Several Other, Independent Reasons As Well

Even if plaintiffs' claims are not preempted, which they are, plaintiffs' complaint also is subject to dismissal for several additional reasons.

1. Plaintiffs' Claims are Barred by the Doctrine of Primary Jurisdiction

Primary jurisdiction "is a prudential doctrine under which courts may, under appropriate circumstances, determine that the initial decision-making responsibility should be performed by the relevant agency rather than the courts." *Syntek Semiconductor Co., Ltd. v. Microchip Tech. Inc.*, 307 F.3d 775, 780 (9th Cir. 2002). The Ninth Circuit has articulated several factors in determining the application of the

[4] Because the FDA has expressly regulated the nutrient content claims at issue, and because plaintiffs' claims seek to supplant these express regulations, this case is distinguishable from those situations in which courts have declined to find preemption by the NLEA. *See, e.g.*, *Lockwood v. Conagra Foods, Inc.*, 597 F. Supp. 2d 1028, 1034 (N.D. Cal. 2009) (explaining that "all natural" claims were not preempted where the FDA "has declined to adopt any regulations governing this term"); *Hitt v. Arizona Beverage Co.*, No. 08cv809, 2009 WL 449190, at *5 (S.D. Cal. Feb. 4, 2009) (no preemption where defendants did "not reference any express preemption provision that applies to plaintiff's claims" challenging the use of the term "all natural" and the use of "fruit names" in defendants' beverage names); *In re Farm Raised Salmon Cases*, 42 Cal. 4th 1077, 1098 (Cal. 2008), *cert denied Albertson's, Inc. v. Kanter*, 129 S. Ct. 896 (2009) (permitting "private remedies" where plaintiffs alleged "violations of state laws identical to the F[F]DCA" in context of claims of artificial colored farmed salmon).

primary jurisdiction doctrine, including "(1) the need to resolve an issue that (2) has been placed by Congress within the jurisdiction of an administrative body having regulatory authority (3) pursuant to a statute that subjects an industry or activity to a comprehensive regulatory authority that (4) requires expertise or uniformity in administration." *Id.* at 781.

This case falls squarely within the primary jurisdiction doctrine. The FDA has regulatory authority over statements regarding the cholesterol and TFA content of packaged goods, has issued specific regulations regarding cholesterol and TFA statements on labels, has issued specific regulations regarding nutrient content statements on the front of packages, and has indicated its intent to continue to refine its regulations of such statements.[5] *See supra* pp. 5-9. The FDA has specialized expertise in the area of cholesterol and TFAs, and has, for example, repeatedly emphasized that amounts of cholesterol below 2 milligrams and TFAs below 0.5 gram per serving are not reliably detectable. *See, e.g.*, RFJN Ex. A, 58 Fed. Reg. at 2332; RFJN Ex. B, 64 Fed. Reg. at 62758; RFJN Ex. C, 68 Fed. Reg. at 41463, discussed *supra* pp. 6-8. Moreover, uniformity in regulation -- rather than piecemeal mandates by courts -- is important to ensuring a system of labeling that will not confuse consumers.

Several recent California federal court decisions have applied the doctrine of primary jurisdiction to dismiss cases similar to this one. For example, in *Aaronson v. Vital Pharmaceuticals, Inc.*, No. 09-cv-1333, 2010 WL 625337 (S.D. Cal. Feb. 17, 2010), the plaintiff alleged that defendant, the manufacturer of energy drinks, violated the UCL and FAL because it "fail[ed] to make known the risks inherent" in the product "by deceptively promoting [it] as having approved and unique drug-qualities"

[5] For example, the FDA is working on the development of additional labeling regulations and has emphasized the importance of maintaining consistency in the labeling system. *See* RFJN Ex. F, Front-of-Pack and Shelf Tag Nutrition Symbols; Establishment of Docket; Request for Comments and Information, 75 Fed. Reg. 22602 (April 29, 2010).

and "disseminated deceptive representations that wrongly promote [the product] as a safe and healthy supplement . . ." *Id.* at *1. The court granted a motion to dismiss these claims under the primary jurisdiction doctrine, reasoning that to evaluate the claims it would "likely need to evaluate conflicting studies and determine whether [the product] and/or it[s] ingredients should be approved as safe" and "[u]nder the primary-jurisdiction doctrine, these issues are best suited for the FDA." *Id.* at *2. The court further explained that application of the primary jurisdiction doctrine was necessary to prevent interference with "uniform regulation in the field of dietary supplements." *Id.* at *3.

Similarly, in *All One God Faith v. Hain Celestial Group, Inc.*, No. C 09-03517, 2009 WL 4907433 (N.D. Cal. Dec. 14, 2009), the district court dismissed under the primary jurisdiction doctrine. Plaintiff, a competitor company, alleged that defendants engaged in unfair competition by selling and marketing cosmetic products using the term "organic." *Id.* at *2. There was no dispute in that case that (unlike here where there are express FDA provisions that apply) the federal government "has declined expressly to impose the NOP [National Organics Program] standards on personal care products," although there had been draft recommendations to the USDA urging the development of a complete federal organic cosmetics program. *Id.* at *5-6. Nevertheless, the district court applied the primary jurisdiction doctrine: "Under the primary jurisdiction doctrine, it would be inappropriate for this Court to assume the USDA's regulatory role, interpret the NOP's regulatory framework, and impose standard that the USDA itself has refused to impose upon Defendants." *Id.* at *7.

In fact, courts consistently apply the doctrine of primary jurisdiction to bar litigation of issues that fall within the province of the FDA. *See Weingberger v. Bentex Pharm.*, 412 U.S. 645, 654 (1973) (appropriate to defer to FDA in action by drug marketers for declaratory judgment, because "questions within the peculiar expertise of an administrative agency [such as the FDA] are appropriately routed to the agency, while the court stays its hand") (internal quotations omitted); *In re*

Human Tissue Prods. Liab. Litig., 488 F. Supp. 2d 430, 433 (D.N.J. 2007) (court should defer to FDA on whether to issue notice, because plaintiffs were "asking the [c]ourt to perform the tasks traditionally relegated to the FDA" and ordering notice could lead to "inconsistent notices"); *Bernhardt v. Pfizer, Inc.*, No. 00 Civ. 4042, 2000 WL 1738645, at *3 (S.D.N.Y. Nov. 22, 2000) (applying primary jurisdiction doctrine and deferring to FDA on sending out emergency notice to prescription drug holders because of "the potential for inconsistent directions").

This Court similarly should not supplant the role of the FDA, particularly where the FDA already has specifically regulated cholesterol and TFAs.

2. This Court Should Abstain in Deference to the FDA

Courts also simply decline to exercise jurisdiction where it would entangle them in an area subject to legislative or regulatory authority. *See Center for Biological Diversity, Inc. v. FPL Group, Inc.*, 166 Cal. App. 4th 1349, 1371 (Cal. Ct. App. 2008) (abstaining where "[i]ntervention by the courts . . . not only would threaten duplication of efforts and inconsistency of results, but would require the court to perform an ongoing regulatory role as technology evolves and conditions change"); *Desert Healthcare Dist. v. PacifiCare, FHP, Inc.*, 94 Cal. App. 4th 781, 794-96 (Cal. Ct. App. 2001) (abstaining in action involving UCL claim); *Wolfe v. State Farm Fire & Cas. Ins. Co.*, 46 Cal. App. 4th 554, 568 (Cal. Ct. App. 1996) ("The [issues] . . . are peculiarly matters within the legislative domain. The Legislature's expressed intent to address these issues, both now and in the future, mandates judicial restraint as much if not more so than had it refused to do so. . . . [W]e decline the invitation to undo what the Legislature has done."); *cf. Korens v. R.W. Zukin Corp.*, 212 Cal. App. 3d 1054, 1058 (Cal. Ct. App. 1989) ("[W]e . . . do not believe that we can properly create by implication a law requiring the payment of interest on security deposits when the Legislature has declined to do so.").

Courts have found abstention particularly appropriate where adjudication would interfere with FDA regulation. In *Gatherer v. Purdue Pharma L.P.*, No. BC

257852, 2002 WL 32144622 (Cal. Super. Ct. Dec. 13, 2002), the court held that abstention was appropriate where plaintiffs brought an action against a pharmaceutical manufacturer alleging misrepresentations or omissions regarding the appropriate uses, risk, and safety of the drug OxyContin. *Id.* at *1. The court explained:

> If this Court were to exercise jurisdiction over this matter, it would improperly intrude into the prescription drug industry that the federal government heavily regulates.
>
> Abstention applies here where the remedy, if granted, has ramifications extending throughout an industry to such a degree that it would endanger the judiciary in a protracted nature of policy formulation and enforcement. Equity relief would be impossible and difficult to administer.
>
> This is a national problem which has many ramifications and this court abstains . . . because the matters raised in Plaintiff's complaint was subject to substantial regulation by the federal government.

Id..

Here, the abstention doctrine applies with particular force. The FDA both: (1) has specifically regulated in this area; and (2) has indicated its intention to continue refining labeling requirements in the future. *See supra* pp. 5-9, 12. Yet, plaintiffs ask the Court to intervene in the FDA's regulatory scheme and to second guess its determination of the circumstances in which the terms "cholesterol free" and "0 Grams Trans Fat" per serving may be used. The FDA -- with its specialized expertise in cholesterol, TFAs and product packaging -- simply is better equipped to develop a uniform scheme of regulation.

3. Plaintiffs Fail to Allege the Requisite Injury in Fact for Standing

Plaintiffs' claims also fail for the independent reason that Plaintiffs have not -- and cannot -- allege facts sufficient to demonstrate standing, as their claims are entirely premised on speculative injury. No plaintiff can obtain any relief in an action brought in federal court unless that plaintiff can allege and demonstrate as a threshold matter that he or she satisfies the standing requirements imposed by Article III. *See*,

e.g., *Summers v. Earth Island Inst.*, 129 S. Ct. 1142, 1149 (2009) ("[Plaintiff] bears the burden of showing that he has standing for each type of relief sought."). To show standing, a plaintiff must allege that "he is under threat of suffering 'injury in fact' that is concrete and particularized; the threat must be actual and imminent, not conjectural or hypothetical; it must be fairly traceable to the challenged action of the defendant; and it must be likely that a favorable judicial decision will prevent or redress the injury." *Pollack v. U.S. Dep't of Justice*, 577 F.3d 736, 739 (7th Cir. 2009); *see also Valley Forge Christian Coll. v. Ams. United for Separation of Church & State, Inc.*, 454 U.S. 464, 472 (1982) (explaining that Article III's standing requirement demands that each plaintiff "show that he personally has suffered some actual or threatened injury as a result of the putatively illegal conduct of the defendant") (citations and quotations omitted).

The Ninth Circuit recently affirmed dismissal in a case similar to this one on the basis that the plaintiffs had failed to satisfy this injury-in-fact requirement. In *Birdsong v. Apple, Inc.*, 590 F.3d 955 (9th Cir. 2009), consumers brought a class action lawsuit alleging that Apple's iPod was defective because it poses an unreasonable risk of hearing loss to users. *Id.* at 956. The Ninth Circuit affirmed dismissal of plaintiffs' claims because the plaintiffs failed to "allege[] the requisite injury in fact to have standing." *Id.* at 960. Specifically, the court concluded that plaintiffs had not alleged a physical injury to themselves, that any alleged injury was purely hypothetical, and that the alleged economic harm did not constitute injury in fact. *Id.* at 960-62. *See also Rivera v. Wyeth-Ayerst Laboratories*, 283 F.3d 315, 319 (5th Cir. 2002) (no injury-in-fact to create standing where plaintiff claimed that she "would like her money back" for having purchased a product that failed to make certain disclosures and allegedly was defective.)

Additionally, in *Koronthaly v. L'Oreal USA, Inc.*, No. 08-4625, 2010 WL 1169958 (3d Cir. March 26, 2010), the Third Circuit affirmed dismissal of claims factually analogous to those in this case. Plaintiff filed a purported class action,

alleging that she was "misled into purchasing unsafe lipstick products," despite the fact that the FDA had determined that "the lead levels in the [d]efendants' lipsticks were not dangerous and therefore did not require warnings." *Id.* at *2. Notably, the plaintiff had alleged that "had she known of the lead she would not have purchased the products." *Id.* at *1. The Fifth Circuit found the plaintiff's allegations insufficient to demonstrate "a concrete injury-in-fact." *Id.* at *2.

Here, plaintiffs allege that the statements "A Cholesterol Free Food" and "0g Trans Fat Per Serving" are misleading. (FAC ¶¶ 62, 65, 66, 68.) Plaintiffs dress up their complaint with extensive discussions of purported evidence of the dangers of cholesterol and artificial TFAs. (*Id.* ¶¶ 19-61.) However, nowhere does the FAC provide factual allegations to support any assertion that plaintiffs suffered or are under threat of suffering a "concrete and particularized" injury as a result of purchasing the products. Instead, plaintiffs generically assert that "[a]bsent Kroger's deceptive claims and fraudulent omissions, Plaintiffs and class members would not have purchased" Kroger's products. (FAC ¶ 74.) But this bare allegation, like the bare allegations in *Birdsong*, *Rivera* and *Koronthaly*, does not explain how plaintiffs suffered any concrete injury from purchasing Kroger's products as a result of the alleged "misrepresentations." Accordingly, Plaintiffs fail to satisfy the Article III standing requirements.

4. *Cel-Tech*'s Safe Harbor Bars Plaintiffs' UCL and FAL Claims

The California Supreme Court has instructed that if a legislative or regulatory body has permitted certain conduct, courts may not override that determination. *See Cel-Tech Commc'ns, Inc. v. Los Angeles Cellular Tel. Co.*, 20 Cal. 4th 163, 182 (Cal. 1999) ("Courts may not simply impose their own notions of the day as to what is fair or unfair. . . . If the Legislature has permitted certain conduct or considered a situation and concluded no action should lie, courts may not override that determination. When specific legislation provides a 'safe harbor,' plaintiffs may not use the general unfair competition law to assault that harbor.").

Courts have consistently applied *Cel-Tech's* 'safe harbor' concept to bar claims like those here. *See, e.g., Rubio v. Capital One Bank (USA), N.A.*, 572 F. Supp. 2d 1157, 1168 (C.D. Cal. 2008) (bank's credit card disclosures that comply with Truth in Lending Act cannot violate UCL); *Suzuki v. Hitachi Global Storage Technologies, Inc.*, No. C06-07289, 2007 WL 2070263 at *4 (N.D. Cal. July 17, 2007) ("[D]efendant's use of the decimal standard [for a 'gigabyte'] on its product packaging was clearly permitted by the legislature, thus bringing it within the safe harbor doctrine of *Cel-Tech*.").

Here, the FDA has specifically concluded that the use of the phrases "cholesterol free" and "0g Trans Fat" per serving are appropriate in connection with label disclosures. 21 C.F.R. § 101.9(c) and (d); § 101.13; and § 101.62. Plaintiffs cannot "assault th[e] harbor" of FDA regulations through the guise of general unfair competition law. *See Cel-Tech*, 20 Cal. 4th at 182.

5. Plaintiffs Fail to Plead Sufficient Allegations to Support a Claim

It is well-established that claims sounding in fraud -- such as plaintiffs' claims here -- must be pled with particularity. *Kearns*, 567 F.3d at 1124 (holding claims under CLRA and UCL failed to satisfy Rule 9(b)); *Wright v. General Mills, Inc.*, No. 08cv1532L, 2009 WL 3247148, at *6 (S.D. Cal. Sept. 30, 2009) (applying Rule 9(b) particularity requirement to CLRA and UCL claims); *Marolda v. Symantec Corp.*, 672 F. Supp. 2d 992, 1005 (N.D. Cal. 2009) (dismissing CLRA, FAL, and UCL claims that failed to meet the Rule 9(b) standard). This same standard applies to allegations of omissions. *Kearns*, 567 F.3d at 1126-27. "Rule 9(b) applies not only to claims in which fraud is an essential element, but also to claims grounded in allegations of fraudulent conduct." *Hoey v. Sony Elecs. Inc.*, 515 F. Supp. 2d 1099, 1102 (N.D. Cal. 2007) (citing *Vess v. Ciba-Geigy Corp., USA*, 317 F.3d 1097, 1103-04 (9th Cir. 2003)). "Rule 9(b) demands that the circumstances constituting the

alleged fraud be specific enough to give defendants notice of the particular misconduct . . . . Averments of fraud must be accompanied by the who, what, when, where, and how of the misconduct charged." *Kearns*, 567 F. 3d at 1124 (citations and quotations omitted).

Here, plaintiffs' FAC does not come close to meeting this standard. Plaintiffs do not allege the specific misrepresentations that each plaintiff allegedly saw, nor in what way they relied upon the information.[6] Plaintiffs assert, without explanation, that "[a]bsent Kroger's deceptive claims and fraudulent omissions, Plaintiffs and Class members would not have purchased" Kroger's products. (FAC ¶ 74.) But they say nothing about the specific products each of them purchased or when they purchased them; what representations they each allegedly read (and which representations they did not see, such as those in the Nutrition Facts box that state the same information as opposed to the "misleading" statements on the front of the label); or what misstatements they each purportedly relied upon in making their purchasing decisions.

Plaintiffs' allegations regarding the statement "A Cholesterol Free Food" highlight their pleading failure. Plaintiffs allege that that statement is misleading because it "capitalizes on a common misperception of the relative importance of dietary cholesterol to fool consumers who are concerned about heart health . . . ." (FAC ¶¶ 63, 67.) Plaintiffs also assert that Kroger "impl[ies] a connection between dietary cholesterol and disease where none exist." (FAC ¶ 60.)

But these allegations are patently nonsensical in that plaintiffs baselessly conclude that Kroger implies and insinuates an array of messages by simply re-printing on its product packaging the content, as defined under FDA regulations, of

[6] Plaintiffs are required to plead reliance on the purported misrepresentations. *See In re Tobacco II Cases*, 46 Cal. 4th 298, 326 (Cal. 2009) ("Therefore, we conclude that this language imposes an actual reliance requirement on plaintiffs prosecuting a private enforcement action under the UCL's fraud prong.").

certain nutrients. Plaintiffs' strained theory appears to be that any statement about the ingredients or content of a product becomes "misleading" -- even if true -- simply because consumers might derive independent conclusions about the product. Such illogical, conclusory allegations fail to satisfy the pleading requirements. *Cf. Rosen v. Unilever*, No. C09-02563 JW, 2010 U.S. Dist. LEXIS 43797 (N.D. Cal. May 3, 2010) (granting motion to dismiss similar action where allegations in complaint were fundamentally illogical).

These types of allegations are indistinguishable from those in *Wright v. General Mills*, 2009 WL 3247148, where the complaint asserted that "[a]s a direct result of its misleading, deceptive, untrue advertising and its unlawful, unfair and fraudulent business practices . . . . Defendant caused Plaintiff and other members of the Class to purchase, purchase more of, or pay more for, these Nature Valley products." *Id.* at *5 (quotations omitted). The *Wright* court found that these allegations failed to satisfy the pleading standard of Rule 9(b). *Id.* at *6.

To the extent the FAC attempts to plead an omission of fact, that claim similarly fails. To be actionable, an "omission must be contrary to a representation actually made by the defendant, or an omission of fact the defendant was obliged to disclose." *Daugherty v. Am. Honda Motor Co., Inc.*, 144 Cal. App. 4th 824, 835 (Cal. Ct. App. 2006); *Long v. Hewlett-Packard Co.*, No. C 06-02816 JW, 2007 WL 2994812, at * 8 (N.D. Cal. July 27, 2007) (applying *Daugherty* and dismissing CLRA and UCL claims). Here, the FAC is devoid of any explanation as to what actionable "omission" was made by Kroger. In fact, the FAC makes clear there was no such omission. For example, plaintiffs allege that the ChurnGold product and Value Graham Crackers contain partially hydrogenated oil and that the "process of hydrogenating oils creates artificial *trans* fats." (FAC ¶ 65, 69.) But the FAC does not allege that Kroger concealed hydrogenated oils from the ingredient list, and in fact Kroger clearly listed this information. (*See* FAC ¶¶ 62-68 and accompanying pictures.) Plaintiffs' only allegation of omission -- that the products "contain[]

artificial *trans* fats and Kroger's claim of '0g TRANS FAT PER SERVING' is literally false" (FAC ¶ 65, 69) -- is premised on requiring Kroger to disclose information that in fact contradicts what the FDA requires to be disclosed. *See supra* pp. 7-8. Plaintiffs plead no facts suggesting that Kroger had an affirmative obligation to disclose trace amounts of TFAs below the 0.5 gram threshold (assuming that trace amount even exists here), which the FDA does not consider to be accurately detectable. *See supra* p. 8. In short, plaintiffs fail to plead fraud or misrepresentation with sufficient particularity and their claims should be dismissed.

6. Plaintiffs' Lanham Act Claims Is Barred

Plaintiffs' claim under the Lanham Act (Fourth Cause of Action) is barred for the additional reason that it is black-letter law that consumers do not have standing to allege Lanham Act false advertising claims. Plaintiffs allege that Kroger made "false or misleading statements of fact regarding" the Kroger products' contents, in violation of the Lanham Act, 15 U.S.C. § 1125, *et seq.* (2009). (FAC ¶ 100.)[7] However, the Ninth Circuit has repeatedly held that to have standing to sue under the Lanham Act's false advertising provisions, the plaintiff must be a competitor of the defendant. *See Jack Russell Terrier Network of N. Cal. v. Am. Kennel Club, Inc.*, 407 F.3d 1027, 1037 (9th Cir. 2005) (plaintiff must demonstrate "(1) a commercial injury based upon a misrepresentation about a product; and (2) that the injury is 'competitive,' or harmful to the plaintiff's ability to compete with the defendant"); *Barrus v. Sylvania*, 55 F.3d 468, 470 (9th Cir. 1995) (affirming dismissal of Lanham Act false advertising claim on standing grounds because plaintiffs, "[a]s consumers, . . . have alleged neither commercial injury nor competitive injury").

[7] While the Plaintiffs do not cite a specific section, the allegations appear to be brought under the false advertising prong of the Lanham Act. *See* 15 U.S.C. § 1125(a)(1)(B) (2009). There are no allegations of violation of the "false association" prong, *id.* § 1125(a)(1)(A).

Accordingly, numerous district courts have held that consumers, like the plaintiffs in this case, do not have standing to bring Lanham Act false adverting claims. *See, e.g., Brosnan v. Florida*, No. C09-227 BZ, 2009 WL 1764535, at * 1 n.4 (N.D. Cal. June 22, 2009) (holding that "[t]o the extent that plaintiff intends to assert a false advertising claim under the Lanham Act, that claim is dismissed . . . [because] plaintiff does not allege that he commercially competes with any of the defendants such that he has standing to sue for any false representations"); *Von Grabe v. Sprint PCS*, 312 F. Supp. 2d 1285, 1302 (S.D. Cal. 2003) (dismissing Lanham Act false advertising claim because "consumers do not meet the standing requirement for the Lanham Act") (citing *Barrus*, 55 F.2d at 470). There simply is no question that plaintiffs' Lanham Act claim fails.

V. CONCLUSION

For the above stated reasons, the Court should dismiss the FAC with prejudice.

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ARNOLD & PORTER LLP

By: /s/ Sean Morris
Sean Morris

Attorneys for defendant
The Kroger Co.